REMARKS

In the Office Action, claims 33-36 are rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 5,252,295 (Gluchowski) in view of U.S. Patent No. 5,236,904 (Gerstenberg). Applicant believes that the rejection should be withdrawn at least in view of the reasons set forth below.

Of claims 33-36, claim 33 is the sole independent claim which has been amended as previously provided. Claim 33 recites an ophthalmic formulation in aqueous solution for topical administration including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. Support for the amendment can be found in Applicant's specification, for example, on pages 18 to 20 in Examples 1 and 2. Claims 34-36 depend from claim 33.

Even assuming that the references are properly combinable, Applicant believes that the alleged combined teachings fail to teach or suggest the claimed invention. As previously discussed, the claimed invention is directed to an ophthalmic formulation in aqueous solution for topical administration with an active phentolamine compound that can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Published Specification (US2004/0176408), Examples 1 and 2 and Tables 1 and 2, beginning on page 6. Moreover, such unexpected results are further supported by an Affidavit of Gerald Horn, M.D. that was previously submitted in this case.

At best, Gluchowski indicates that oxazoline or imidazoline compounds are preferred (See, Gluchowski, col. 3, lines 39-41), but nowhere does Gluchowski specify an ophthalmic formulation that includes a pharmaceutically active compound consisting essentially of phentolamine and in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness as required by the claimed invention. Indeed, Gluchowski is directed to intraocular pressure and not reduction in pupil size, let alone the reduction of pupil size in dim

light to improve vision in dim light where redness is further minimized as required by the claimed invention. Again, Applicant has demonstrated the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations.

Further, the Gerstenberg reference fails to recognize the unexpected benefit of phentolamine in an ophthalmic formulation, let alone a phentolamine-based ophthalmic formulation in aqueous solution for topical administration that can effectively reduce pupil size in dim light to improve vision. Indeed, this reference is directed to a different application that requires a different type of formulation via a different route of administration, e.g., treatment of sexual dysfunction via injection of a peptide N-terminal histidine C-terminal methionine amide. See, Gerstenberg Abstract.

Moreover, the Patent Office has improperly relied on Applicant's alleged admission (see, Office Action, pages 2-4) to fill in the gap between the subject matter as claimed and as disclosed in the cited references. Indeed, this reliance on Applicant's alleged admission is a clear example of improper hindsight as a basis to justify the combination/modification of the references in the first place. Again, Applicant has demonstrated the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations, clearly unrecognized by the cited references. Therefore, Applicants believe that the Patent Office has failed to establish a *prima facie* case of obviousness, and thus respectfully request that the obviousness rejection be withdrawn at least in view of same.

Applicant notes that a supplemental information disclosure statement (IDS) is being submitted concurrently with this Response. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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